

Remarks

Claims 9, 11, 12, 14, 16, 23-27, and 44-47 were pending in the application. By this amendment, claims 16 and 27 are cancelled and claims 48-50 added. Therefore, claims 9, 11, 12, 14, 23-26, and 44-50 are now pending.

Support for the new claims and the claim amendments can be found throughout the specification, for example:

Claim 9: claim 16, original claim 9, and page 5, line 19.

Claim 23: claim 27, claims as originally filed, and page 5, line 19.

Claims 14, 26, 44 and 47: claims as originally filed, and page 5, line 19.

Claims 48-50: page 9, line 31.

No new matter is added by this amendment.

Telephone interview summary

Applicants thank Examiner Whitman and Primary Examiner Joe Woitach for a telephone interview with Applicants' representative Sheree Lynn Rybak on September 1, 2005. During this telephone interview, all of the claim rejections were discussed.

With regards to the 35 U.S.C. § 112, first paragraph rejections, it was agreed that the rejections would be withdrawn if the phrase "a nucleic acid encoding hepatocyte growth factor" was amended to "hepatocyte growth factor gene;" the language used in the claims as originally filed. In addition, Applicants' representative noted that support for the phrase "at least 50 µg" could be found in the claims as originally filed (such as original claims 8 and 21), and that support for the phrases "once every few weeks" and "once every few days" could be found on page 9, line 33. Therefore, the Examiners agreed that the "at least 50 µg," "once every few weeks" and "once every few days" language in the claims was acceptable.

With regards to the 35 U.S.C. § 103 rejections, it was agreed that incorporation of the "at least 50 µg" language into claims 9 and 23 would overcome the rejections, as claims 16 and 23 were found to be free of the prior art.

35 U.S.C. § 112, first paragraph rejections

Claims 9, 11, 12, 14, 16, 23-27, and 44-47 were rejected as failing to comply with the written description requirement. Applicants respectfully disagree and request reconsideration.

In order to expedite prosecution, the phrase “a nucleic acid encoding hepatocyte growth factor” was amended to “hepatocyte growth factor gene.” The “gene” language was used in the claims as originally filed. Therefore, no new matter is added by this amendment.

The phrase “at least 50 µg” does not include new matter, as this exact phrase is found in original claims 8 and 21 of the application.

Literal support for the phrases “once every few weeks” and “once every few days” is found on page 9, line 33 of the specification.

In view of the amendment and the above explanations, Applicants request that the 35 U.S.C. § 112, first paragraph rejections be withdrawn.

35 U.S.C. § 103 rejections

Claims 9, 11, 12, 14, and 23-26 were rejected as obvious in view of the prior art. Although Applicants disagree, in order to expedite prosecution, claims 9 and 23 have been amended to include the phrase “at least 50 µg”. This phrase was present in claims 16 and 27, which were found to be free of the prior art.

In view of the amendments, Applicants request that the 35 U.S.C. § 103 rejections be withdrawn.

Information Disclosure Statement

An Information Disclosure Statement (IDS) is submitted with this response. The IDS discloses Morishita et al., *Hypertension* 2004;44:203-209, which presents Phase I/IIa clinical data from clinical gene therapy using HGF to treat diabetic ischemic disease. As shown in Table 1 under the heading “Risk Factor Classification,” Patient Nos. 2 and 6 had diabetes mellitus with arteriosclerosis obliterans with arterial occlusions. Table 2 shows the results of gene therapy, indicating that No. 6 showed partial healing of ischemic ulcers and both patients experienced reduction of rest pain.

If any matters remain before a Notice of Allowance is issued, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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